

Reprocessed by



## Instructions for Use Reprocessed Non Sterile External Fixation Devices

### Reprocessed Device for Single Use

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

#### Explanation of Icons

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Date of Reprocessing

REF

Ascent Product Code



Do Not Reuse



See Instructions For Use

# Reprocessed Non Sterile External Fixation Devices

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## External Fixation Devices Description

External fixation devices are specially designed frames, clamps, rods, rod-to-rod couplings, pins, posts, fasteners, wire fixations, fixation bolts, washers, nuts, hinges, sockets, connecting bars and screws used for the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. Materials used include metal alloys, plastic and composites. These materials are chosen to address a wide range of fractures and applications as well as to allow for the appropriate amount of rigidity and stability.

## Zimmer TransFx™ Description

The TransFx™ External Fixation System is a modular system. The system design is designed to provide options in frame construction, simplicity in frame components, and ease of transition from one frame size to another.

**NOTE:** Ascent Healthcare Solutions only reprocesses the external parts of the systems. The pins that are inserted through the skin to the bone are not reprocessed.

## Indications for Use

Reprocessed external fixation devices are indicated for use in patients requiring external skeletal fixation and treatment of fractures, osteotomy, arthrodesis, correction of deformities, fracture revision, bone reconstruction procedures, limb lengthening, correction of bony or soft tissue deformities and segmental bony or soft tissue defects.

## Zimmer TransFx™ Indications for Use

Zimmer TransFx™ External Fixation Devices are indicated for fractures of the long bones and pelvis, joint fusion, limb lengthening, osteotomies, and periarticular fractures.

## Contraindications for Use

Reprocessed external fixation devices are contraindicated for the following:

- When there is an active infection.
- For disabled or non-compliant individuals who cannot perform the necessary postoperative care.
- Fractures that will heal satisfactorily with conservative treatment.

Reprocessed external fixation devices are relatively contraindicated for use in patients with the following:

- Known sensitivity and/or allergies to the materials in the external fixation device model to be used.
- History of frequent infections.
- Neuromuscular deficiencies.
- Significant deficiency in bone quantity and quality.
- Inadequate or impaired blood flow in the body site(s) to be treated.
- Malignant bone growth in fracture area.
- Obesity that could lead to the failure of the device.

## Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with techniques associated with the orthopedic surgical procedure employed. For further information about techniques, complications and hazards, consult the medical literature.
- The use of these devices requires a thorough understanding of the techniques and principles of orthopedic surgery procedures.
- Projectiles from wire or pin cutting could cause injury to patient or medical personnel during surgery.
- Preoperative frame assembly and adequate supply of components is recommended.
- Intraoperative fracture or breakage of instruments can occur (e.g. due to excessive force, extensive use). Inspect all external fixation devices and components prior to surgery. Replace when necessary.
- As a part of the preoperative preparation and surgery planning phase it is advisable to anticipate varus, valgus, procurvatum and recurvatum distraction by selection of an appropriate prophylactic ring tilt and strategically positioning of wires with stoppers, fulcrums, half pins, and hinges.
- Avoid damage to nerves, muscles, tendons, and vessels by careful placement of wires and pins.
- Avoid heat necrosis of surrounding tissue and bone by drilling wires slowly through the bone.
- Hold wire tips when clipping and wear eye protection. Handle the sharp tips of wires with caution.
- Maintain meticulous daily pin and wire site care management to prevent infection.
- Use periodic postoperative follow-ups and radiographs to monitor the distraction phase.

## Reprocessed Non Sterile External Fixation Devices

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### Precautions

- Ensure compatibility of all devices used in a single procedure.
- Select the appropriate model and material of external fixation component(s) for the patient's treatment needs as well as the clinical outcome desired.
- Do not apply excessive force to external fixation devices.
- Some of the materials used in external fixation devices could interfere with MRI equipment.
- Use utmost care in handling and storing of devices to prevent cutting, bending or scratching of the device.
- Securely fasten all wires and miscellaneous parts. Refer to product literature for the tensioning of wires.
- Use a wire diameter with sufficient strength for maintaining the appropriate axial stiffness of the device. Recommended wire diameters: 1.8 mm for tibia and femur in normal adults; 1.5 mm wires for upper limbs and pediatric lower limb applications.
- Allow for patient limb swelling when choosing sizes of rings, half rings and frames. Four centimeters greater than the patient's limb diameter is recommended.
- Routinely check the security of wires and pins, the tension of wires, and the overall integrity of frame components.
- Preoperative Care
  - Preparation should include provision of a sufficient surplus supply of sterile components.
  - Ensure proper tightening of screws.

### Postoperative Care

- Advise the patient of the importance of complying with:
  - The surgeon's warnings and recommendations regarding the use and daily care of the external fixation devices, including topical cleaning using 2% hydrogen peroxide solution in sterile water and routine showering with antibacterial soap.
  - Daily cleansing of pin-skin interface,
  - The limitations in weight bearing as compared to that of a normal, healthy bone,
  - The limitations of activity levels and
  - The medical follow-up required.
- Advise the patient to report unanticipated reactions or problems without delay.
- Visualize and reevaluate the bone healing progress and arrange for adjustments accordingly.
- When applicable, touch down weight bearing may be allowed after surgery and gradually increased as the callus thickens and matures.
- Weekly to biweekly follow-up and radiographs are recommended during the distraction phase.

### Adverse Reactions

- Injury of nerves or vessel.
- Edema.
- Premature bone consolidation.
- Osteomyelitis.
- Damage to soft tissue (e. g. tendons or ligaments).
- Abnormal growth plate development (in patients who are skeletally immature).
- Necrosis due to bone screw or wire insertion.
- Pin loosening.
- Excessive operative bleeding.
- Intractable pain.
- Vascular disorders (thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis).
- Compartment syndrome.
- Fracture of regenerated bone.
- Bone deformity.
- Chronic drainage of bone screw or wire sites after device removal.
- Inadequate fracture reduction because of failure to pin the bone segments correctly.
- Failure of bone to regenerate satisfactorily.
- Ankle stiffness (if multiple transfixion pins are used in tibial fractures).
- Deep or superficial infection.
- Thrombosis, late erosion or arteriovenous fistulas.
- Loss of bone mass.
- Septic Arthritis.
- Another operation to replace or change the device.
- Foreign body reaction or metal sensitivity.
- Neurological complications, including possibly palsy.
- Pressure problems caused by external components.
- Limb length discrepancy.
- Intrinsic risks associated with anesthesia.
- Tissue necrosis.
- Pin breakage or movement at the fracture site caused by use of too few pins or pins that are too small.
- Nonunion or pseudoarthrosis.
- Bone damage.
- Equinus deformity.
- Joint contracture, subluxation, dislocation or loss of range of motion.
- Excessive motion at the fracture site caused by failure to tighten the component parts of the device.
- Bone separation induced by rapid drilling of the bony cortex.

## Reprocessed Non Sterile External Fixation Devices

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### Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device to Ascent Healthcare Solutions if it is not in acceptable condition for surgery.

### 3. Sterilization

Unless otherwise noted, Ascent external fixation components are provided NON-STERILE. All NON-STERILE components must be properly sterilized following the recommended sterilization procedures:

Method	Cycle	Temperature	Time
Steam	Pre-Vacuum	132°C 270°F	18 minutes

Sterilizer manufacturer recommendations should always be followed. Sterility cannot be assured if the sterilization tray is overloaded. When sterilizing multiple instrument sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.

Note: Steam sterilization is not recommended for any plastic component.

Caution is recommended during sterilization and storage so as to prevent contact with metal or other hard objects that could damage the finish or prevent proper assembly.

4. Before beginning the procedure, verify compatibility of all devices and accessories to be employed in the planned surgical procedure.
5. Use the pins that are compatible with the external fixation system being used. Ascent Healthcare Solutions does not provide pins.
6. Place the components to be used in a sterile work area using aseptic technique.
7. Consider preliminary frame assembly to shorten the procedure.
8. Verify if the product supply is sufficient to complete the intended procedure.
9. Follow a suitable orthopedic surgery protocol.
10. Securely fasten all components.
11. Device is intended for single use during a single patient orthopedic procedure.

### Storage and Handling

- Store in a dry environment. The devices should never be stored in a wet or moist condition.

## Reprocessed Non Sterile External Fixation Devices

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### Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

Zimmer TransFx™ is a trademark of Zimmer Holdings, Inc.